(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 125 596 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
11.05.2005 Bulletin 2005/19

(51) Int Cl.[7]: **A61M 25/06**, A61M 39/06, A61M 39/28

(21) Application number: **01301049.1**

(22) Date of filing: **06.02.2001**

(54) **Intravascular catheter**

Intravaskulärer Katheter

Cathéter intravasculaire

(84) Designated Contracting States:
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR

(30) Priority: **16.02.2000 JP 2000038725**

(43) Date of publication of application:
22.08.2001 Bulletin 2001/34

(73) Proprietor: **TERUMO KABUSHIKI KAISHA**
Tokyo (JP)

(72) Inventors:
- **Toyokawa, Yoshihide**
Nakakoma-gun, Yamanashi (JP)
- **Ishikawa, Kenji**
Isehara-shi, Kanagawa (JP)
- **Asai, Toshiya**
Sagamihara-shi, Kanagawa (JP)

(74) Representative: **Harrison, David Christopher et al**
Mewburn Ellis LLP
York House
23 Kingsway
London WC2B 6HP (GB)

(56) References cited:
EP-A- 0 312 073
EP-A- 0 691 139
US-A- 4 198 973
US-A- 4 687 176
US-A- 4 834 719
US-A- 5 167 635
US-A- 5 270 003
US-A- 5 429 616
US-A- 5 749 859

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates to an intravascular catheter provided with a function for controlling the blood flow.

[0002] Insertion of an intravascular catheter in a blood vessel can be confirmed by flashback, that is, the backward flow of the blood at the time of piercing the intravascular catheter into the blood vessel. However, a problem of leakage of the blood flowing backward arises at the time of pulling out the internal needle. In order to cope with the problem, conventionally, a method of stopping the blood by pressing the tip end part or the hub base part of the intravascular catheter, a method of preventing the blood leakage by providing an elastic tube at the catheter base end part and pressing the tube part with a finger at the time of pulling out the internal needle, and a method of preventing blood leakage by storing an elastic tube with a swelling in the catheter base end part and pressing the swelling part (U. S. Patent No. 3,856,010) have been proposed. FIGS. 13 and 14 show the conventional method of restraining the leakage by directly pressuring the catheter part outer surface in the vicinity of the hub base of the intravascular needle with a finger. However, since the method of directly pressuring the catheter outer surface is a method of closing the catheter itself by flattening the same with the pressure, there is a risk of breaking the catheter itself by the flattening operation so as to lead to cut-off of the catheter. Moreover, intravascular catheters comprising a means for directly pressing and closing the catheter base end part outer surface (U. S. Patent Nos. 5, 108, 374 and 5, 542, 933) have been proposed, but since the catheter part is pressured directly in these methods, catheter breakage may be brought about.

[0003] Furthermore, since the above-mentioned methods involve the pressure from above so as to apply the pressuring force to the vicinity of the insertion part, the blood vessel, and the skin of the patient, a problem is involved in that the patient suffers the great pain.

[0004] As a means for preventing the blood leakage without giving a pain to the patient, a method of providing a blood flow controlling device such as a check valve, a detent plug, and forceps stoppage in an elastic tube part can be presented. Examples of the methods include a method of further providing an elastic clamp tube part between a hub part at the catheter base end part and a connector part as a part for connecting with an external circuit so as to enable closure with forceps (JP-B-61-25490U, JP-B-6-39724U). However, in the case of using a tool such as metal forceps, since the elastic clamp tube is fixed firmly by clamping, there is a risk of ruining the elastic clamp tube part to cause breakage as in the above-mentioned methods so as to lead to leakage of the blood or the transfusion liquid. Moreover, since the forceps are bulky, the hand can be uncertain so that the safe and certain operation may be prevented. Furthermore, there is a risk of fall-off of the inserted catheter due to self weight of the forceps when the operator leaves the hand. Moreover, since the method requires the elastic clamp tube part between the hub part and the connector part, the number of parts is increased so that the production and assembly is complicated as well as the equipment cost is increased as well. Furthermore, since the length of the hub part and the connector part is prolonged for the clamp tube, a problem is involved in that the operativity and the handling convenience are deteriorated due to the bulkiness.

[0005] As a means for preventing the blood leakage without using forceps, a method of providing wing parts between the hub and the connector, and nipping the wings of both sides so as to pressure and close the elastic tube (JP-B-1-15308, JP-A-8-141078, JP-W-9-509075) has been proposed. However, also in the method, the problems are not solved such as increase in the number of parts due to necessity of the elastic tube part between the hub part and the connector part, complication of the production and assembly so as to increase the equipment cost, and prolongation of the hub part and the connector part so as to cause bulkiness and operation difficulty.

[0006] As another problem, since the method of pressuring the catheter part with a finger, and the method of pressuring and closing by wings require the holding or nipping operation with one hand for fixing and maintaining the pressured state, there is a risk of inadvertent piercing by the internal needle after pulling off, or connection mistake at the time of connecting the circuit due to insufficient attentiveness.

[0007] US-A-5429616 discloses a catheter having a hub containing a tube of resiliently compressible sealing material. Around this tube is a side wall which is collapsed, to compress the tube, by means of grippable locking members which extend tangentially parallel to each other. The locking members may have latch means to lock them in the compression mode. US-A-5749859 shows a similar structure in which foldable wings of a hub squeeze a flexible tube.

[0008] EP-A-312073 describes a catheter having a valve with a flexible tubular insert in two portions which are mutually displaceable from their coaxial position by tilting one relative to the other and shaped to compress the tubular insert when so displaced.

[0009] US-A-4198973 shows a catheter having a hub around it to which are attached two projecting wings. The wings can be folded together by bending at a hinge line in one wing so that a protuberance on this wing presses on the hub to occlude the catheter. The wings can be locked in the folded position.

[0010] EP-A-691139 shows an elastic clip having wings which are pressed and locked together to compress and close a flexible tube, particularly in medical uses.

Summary of the Invention

[0011] In view of the above-mentioned circumstances, an object of the invention is to provide an intravascular catheter capable of closing the catheter part without breaking the catheter part by pressuring the catheter part via a flexible resin member provided on the outer surface of a catheter part, and further comprising a blood leakage prevention member capable of preventing the blood leakage.

[0012] Moreover, another object is to provide an intravascular catheter comprising a mechanism for easily fixing or releasing the state with the blood leakage prevented by pressuring and closing the catheter

[0013] The invention provides an intravascular catheter as set out in claim 1.

[0014] Preferably the catheter and the flexible resin member are fixed by one of welding, fusion and an adhesive.

[0015] Preferably the flexible resin member is a thermally contractible member, fixed on the catheter part outer surface by thermal contraction

[0016] Preferably a hub is provided on the proximal end of the flexible resin member

[0017] Preferably the flexible resin member has a tubular shape with a rhomboidal cross-sectional shape, the ratio A/B of the thickest part A and the thinnest part B of the tube wall being in the range between 1 and 10

[0018] Preferably the flexible resin member has a tubular shape, with an elliptical cross-sectional shape, the ratio C/D of the longer axis C and the shorter axis D in the range between 1 and 4

Brief Description of the Drawings

[0019]

FIG 1 is a plan view of an intravascular catheter of the type with a tubular flexible resin member enveloping the end part of the catheter base, to which the invention is applied

FIG. 2 is a side view of FIG 1

FIG 3 is an enlarged view of the A-A' cross-section in FIG. 1

FIG 4 is an diagram showing the operation state at the time of piercing, using an intravascular catheter according to the invention

FIG 5 is a diagram showing the state of pressuring a flexible resin pipe-like member by the wing parts, and fixing and maintaining the pressured and closed state by the fixing mechanism after taking out the internal needle of the intravascular needle according to the invention

FIG 6 is a cross-sectional view taken on the line A-A' in FIG. 1, of an embodiment of the invention with the fixing mechanism in the pressuring state and the releasing mechanism applied

FIG. 7 is a perspective view of an embodiment with a one-touch fixing function applied in the wing parts

FIG. 8 is a perspective view showing an applied embodiment of the fixing mechanism by fitting the projection and recess parts.

FIGS 9(A) to 9(D) are perspective views showing the fixed state by the fixing mechanism and the fixation released state using a nail according to another embodiment of the invention.

FIG. 10 is a cross-sectional view showing an applied embodiment of integral molding of the hub, wings, and connector

FIGS. 11(A) and 11(B) are cross-sectional views of modified embodiments of the flexible resin used in the invention.

FIG. 12 is a plan view showing an embodiment of the invention applied to an introducer kit

FIG. 13 is a diagram showing the operation state at the time of piercing a conventional intravascular catheter into the skin

FIG. 14 is a diagram showing the state of restraining blood leakage by pressuring the catheter base end part by one finger after taking out the internal needle after piercing the intravascular catheter into the skin.

[0020] The invention provides an intravascular catheter comprising a catheter part and an internal needle disposed through the catheter part, with a flexible resin member disposed at the base end part of the catheter part so as to envelop the catheter outer surface. By pressuring and closing the catheter part via the flexible resin member from the outside with an appropriate tool, the blood leakage can be prevented while preventing breakage of the catheter. Furthermore, a blood leakage prevention means for pressuring and closing the catheter part can be disposed in the intravascular catheter main body in the invention.

[0021] The invention will be described in detail with reference to the drawings. The figures referred to show examples, and thus the invention is not limited thereto.

[0022] As shown in FIGS 1 and 2, a catheter part 1 and an internal needle 2 disposed therethrough are provided. An internal needle hub 3 is provided at the rear end of the internal needle 2, and a cap 5 containing a blood leakage resistant filter is further disposed on the rear end thereof. A flexible resin member 4 including a reinforcing tubular or pipe-like member, capable of alleviating the stress concentration, is provided on the base end part of the catheter 1 so as to envelop the catheter 1 outer surface. The position for mounting the flexible resin member onto the catheter is preferably at the catheter base end part. By mounting at the base end part, the part of the catheter inserted and placed in the blood vessel can be longest so that the effect of preventing the bend of the base end part, which is most liable to be bent, can be provided.

[0023] The flexible tubular resin member can provide the breakage prevention effect by the stress concentra-

tion alleviation, and particularly is the pipe-like member 4 shown in FIGS. 1, 2 and 3 (cross-sectional view taken on the line A-A' in FIG. 1). In addition, another example of a flexible resin member is a modified pipe-like member including a slit thereon.

[0024] In the invention, the operativity is further be improved by providing a blood leakage prevention means in the catheter main body. Examples of mounting the blood leakage prevention means include a provision of wing parts in the catheter main body, and pressure parts in the wing parts. The wing parts 6 will be explained specifically with reference to drawings.

[0025] The wing parts are wing-like parts provided between the catheter part and the connector part on the right and left sides. As shown in FIGS. 1 and 2, the wing parts 6 comprise pressure parts 7. Although the pressure parts 7 provided in the wing parts 6 shown in FIG. 3 comprise projected members, any shape can be adopted as long as it can pressure and close the flexible resin member and the catheter part.

[0026] Furthermore, a fixing mechanism as a means for fixing the pressured state as well as a releasing mechanism as a means for releasing the fixed state are further provided, as set out in claim 1. They are not particularly limited, but mechanisms capable of easily fixing and maintaining the fixed state as well as capable of easily releasing the state like those shown in FIGS. 6 and 7 are further preferable. In the embodiment shown in FIG. 6, the fixed state can easily be released by nipping a plate-like part 12 provided elongating outside of a nail part of a wing part at one side, and the wing end part 6 so as to lift the nail part. According to this shape, since the fixed state can be set or released by one hand, it is extremely convenient because it cannot prevent the speedy hand of the medical expert.

[0027] Next, another embodiment of the shape of the wing part will be described. In the wing parts shown in FIG. 8, a projection-shaped part and a recess-shaped part are provided each on the right and left wings so as to achieve fixation of the closed state by fitting the projection part and the recess part. Although the shape of the wing parts is developed into a substantially flat plate-like shape at the time of releasing the fixation in the above-mentioned embodiments of the wing parts, a shape of the wing parts with the rolled state maintained without being spread into a substantially flat plate-like shape at the time of releasing fixation can also be adopted as shown in FIGS. 9(A) to 9(D).

[0028] The pressure parts including the wing parts will be explained. The pressure parts are parts for deforming the flexible resin member and the catheter part. For example, they can be projected members including the wing parts, disposed on the right and left wings at symmetrical positions.

[0029] Furthermore, as shown in FIG. 10, if the flexible resin member is formed integrally with the catheter part or the connector part, since a connection part between the parts can be eliminated, pulling off of the flexible resin member from the catheter part or the connector part can be avoided even if they are pulled by some causes. Moreover, since the gap in the internal space can be reduced, eccentric flow or stagnation can hardly be generated in the blood flow, and thus generation of thrombus can be prevented.

[0030] Furthermore, in the case where a tubular flexible resin member is used, with a rhomboidal, elliptical, or a flat cross-sectional shape as shown in FIGS. 11(A) and 11(B), closure of the pressure parts can be facilitated, and thus it is further effective. As to the specific range of the shape, in the case of the rhomboidal shape, a ratio A/B of the thickest part A and the thinnest part B in the range between 1 and 10 is effective. With a smaller ratio, the strength of the thinnest thick part is weak so that the strength of the flexible resin member cannot be maintained; therefore, it is not preferable. Moreover, in the case of the elliptical cross-sectional shape, a ratio C/D of the longer axis C and the shorter axis D in the range between 1 and 4 is effective. With a larger ratio, the flexible resin member is flattened too much so that the channel is so narrow that the smooth flow of the blood or the transfusion liquid can hardly be ensured; therefore, it is not preferable.

[0031] In the invention, a hub part 9 can be disposed at the base end side (proximal side) of the flexible resin member 4, 11 as shown in FIGS. 1 and 2. The hub 9 can be provided of the same material or continuously with the catheter 1 and the flexible resin member 4 and 11. Furthermore, a connector part 10 is provided at the rear end part of the hub part 9. The connector part can be provided either of the same material or continuously with the hub part 9, but it is more preferable that it is provided continuously therewith. The hub part is a part for bonding the catheter part and the connector part, and the connector part is a part for connecting the intravascular catheter and an external transfusion liquid circuit. Compared with the conventional intravascular catheter including the components in the order of the hub part, the flexible resin member, and the connector part, the intravascular catheter according to the invention including the components in the order of the flexible resin member, the hub part, and the connector part can achieve integration of the hub part and the connector part provided adjacently because the flexible resin member is provided onward with respect to the hub part so that the number of parts can be reduced so as to achieve the compactness as well as the operativity and the handling convenience can further be improved.

[0032] As the part for connecting the wing parts 6 to the catheter part, the hub part 9 can preferably adopted as shown in FIGS. 1 and 2, but it is not limited thereto. That is, it can be the catheter part 1, the flexible resin member 4, 11, or the like, and thus it is not particularly limited as long as it can be fixed to the main body.

[0033] Hereinafter the operation method of the intravascular catheter will be explained.

[0034] As shown in FIGS. 4 and 5, with both wing

parts 6 bent upward, the wing lower surfaces are nipped by fingers so as to have the flexible resin member 4, the end part of the catheter 1, and the internal needle 2 in the state gripped by the pressure parts 7 on both wings.

[0035] Thereafter, the tip end of the internal needle 2 is pierced into the blood vessel. With the internal needle 2 serving as the guide, the catheter 1 is inserted into the blood vessel. Insertion of the internal needle 2 into the blood vessel can be confirmed by flow-out of the blood through the internal needle 2 from the rear end of the internal needle of the internal needle hub 3. Moreover, leakage of the blood flown out to the outside can be prevented by a blood leakage resistant filter of a cap 5 provided at the rear end of the internal hub 3.

[0036] After insertion of the catheter 1 into the blood vessel, the internal needle 2 is taken out from the blood vessel and the catheter 1. In this case, pressure on the wing parts 6 by fingers is released slightly for facilitating the pull-out of the internal needle 2.

[0037] Pressure on the wings 6 by fingers is increased immediately after pulling out the internal needle 2 so that the tip end thereof passes by the wing parts 6 so as to pressure and close the flexible resin member 4, and the end part of the catheter 1 so that blood leakage from the blood vessel out of the connector part 9 via the catheter can completely be prevented. Furthermore, since the closed state can be maintained owing to the fixing mechanism 8, the operator can concentrate on the operation for abandoning the pulled-out internal needle as well as the subsequent operation of connecting the connector part 9 with the external circuit such as a medicine liquid and a transfusion liquid can be executed with both hands.

[0038] After connecting the connector part 9 with the external circuit, the pressured and closed state can be released by releasing the pressure by the fingers or releasing the fixed state by the releasing mechanism 12 in the case where it is fixed by the fixing mechanism 8 so that the wing parts 6 are spread in the initial state so as to fix the wing parts 6 onto the skin surface with a tape.

[0039] As an applied embodiment, the invention can be applied in an intravenous needle, an intra-arterial needle, and a dialyzing needle. Furthermore, it can be applied in an introducer kit and an IVH catheter kit, but it is not limited thereto.

[0040] An embodiment of the operation method as the introducer kit will be described with reference to FIGS. 1, 5, and 12. With the internal needle 2 inserted as shown in FIG. 1, the wing parts 6 are nipped by fingers for inserting the catheter into the blood vessel with the flexible resin member 4 and the internal needle 2 gripped by the pressure parts 7. After pulling out the internal needle, the wing parts 6 are further pressured so as to close the flexible resin member 4. By fixing the closed state by the fixing mechanism 8 so as to be in the state of FIG. 5, the blood leakage is restrained. Furthermore, at the time of introducing an external catheter such as a guide wire 316, after releasing the fixing mechanism 8, the guide wire 316 is introduced with the pressure by the pressure parts gradually released by fingers of one hand. By further inserting the guide wire while further increasing the pressure by fingers at the time the guide wire 316 passes by the pressure parts 7 so as to grip the flexible resin member 4 and the guide wire 316 by the pressure parts, the guide wire 316 can be introduced into the blood vessel while restraining the blood leakage due to backward flow from the blood vessel as shown in FIG. 12.

[0041] The materials used in the invention will be explained.

[0042] As the material for the catheter part, thermoplastic resins such as fluorine resins, urethane resins, nylon resins, polyester resins, polyethylenes, and polypropylenes are preferable, but it is not limited thereto.

[0043] Moreover, the flexible resin member can be made from the same material as the catheter part and the hub part. Furthermore, it can be provided continuously with the hub part. As the material therefor, flexible resins, such as olefin-based elastomers including 1,2-polybutadiene, styrene-based elastomers, urethane resins, polyethylenes, polypropylenes, nylon resins, silicone resins, polyvinyl chloride resins, natural rubbers, and mixtures thereof can be used. Since butyl rubbers and urethane resins can easily alleviate the stress concentrated on the pressure parts, they are preferable for the capability of preventing breakage of the catheter in the pressured and closed state further effectively, but it is not limited thereto.

[0044] In the case urethane resins are used for the materials of both catheter part and flexible resin member, by using a urethane resin having a higher elasticity for the flexible resin member compared with that of the catheter part, release of the pressured and closed state by the fixing mechanism part can be executed smoothly.

[0045] As the material for the wing parts, flexible resins, that is, the materials same as that of the flexible resin member, the hub part, and the connector part can be used. Examples thereof include olefin-based elastomers including 1,2-polybutadiene, styrene-based elastomers, urethane resins, polyethylenes, polypropylenes, nylon resins, silicone resins, polyvinyl chloride resins, natural rubbers, and mixtures thereof, but it is not limited thereto.

[0046] As the material for the pressure parts, the fixing mechanism part, and the releasing mechanism part, both elastic materials and non-elastic materials can be used. Furthermore, it can either be same as or different form the material of the wing parts. Examples of the elastic materials include olefin-based elastomers including 1,2-polybutadiene, styrene-based elastomers, urethane resins, polyethylenes, polypropylenes, nylon resins, silicone resins, polyvinyl chloride resins, natural rubbers, and mixtures thereof, but it is not limited thereto. Examples of the non-elastic materials include engineering plastics such as polysulfones, polyether sul-

fones, polycarbonates, and polyimides, but it is not limited thereto. For example, as other non-elastic materials, metals or alloys such as iron, silver, copper, aluminum and stainless steel can also be used.

[0047] Although the hub part is a part for connecting the catheter part with the connector part, it can be provided continuously with the catheter part or the flexible resin part. The material thereof can be flexible resins, that is, the materials same as that of the flexible resin member. Examples thereof include olefin-based elastomers including 1,2-polybutadiene, styrene-based elastomers, urethane resins, polyethylenes, polypropylenes, nylon resins, silicone resins, polyvinyl chloride resins, natural rubbers, and mixtures thereof, but it is not limited thereto.

[0048] Although the connector part is a part for connecting with the liquid circuit for a medicine liquid or a transfusion liquid, it can be provided continuously with the hub part. The material thereof can be flexible resins, that is, the materials same as that of the flexible resin member. Examples thereof include olefin-based elastomers including 1,2-polybutadiene, styrene-based elastomers, urethane resins, polyethylenes, polypropylenes, nylon resins, silicone resins, polyvinyl chloride resins, natural rubbers, and mixtures thereof, but it is not limited thereto.

[0049] As a method for bonding the catheter part 1 and the flexible resin member, a method of injecting an adhesive into a gap part between the outer surface of the catheter part and the inner surface of the flexible resin member , and curing can be presented. As another example, a method of preliminarily applying an adhesive on the outer surface of the catheter part, placing the flexible resin member thereon, and curing can be presented. It is further preferable to use a photo-curing adhesive, and a method of directing a radioactive ray from an opening part or from the outside for curing can be presented, but it is not limited thereto. Moreover, it is also possible to achieve fusion or adhesion by thermal fusion, high frequency induction heating, or high frequency dielectric heating. Since the circuit restoration force after being released from the closed state is improved in this case, it is further preferable.

[0050] Furthermore, in the case where the catheter part and the flexible resin member are made of the same material, adhesion using an organic solvent is also possible. For example, in the case where a urethane resin is used for the material of the catheter part and the flexible resin member, adhesion can be completed by dropping a few drops of an organic solvent; therefore, the operation can be simple.

[0051] Moreover, as the flexible resin member, a member made from a thermally contractible material can be used. A method of placing a thermally contractible member having an inner diameter larger than the catheter outer diameter on the catheter outer surface, and causing the thermal contraction in an oven or by a drier for fixation on the catheter outer surface can be presented. Since the method is simpler than the method using an adhesion or thermal fusion, it is further preferable, but it is not limited thereto. Examples of the thermally contractible member include thermally contractible members having the elasticity, such as those containing an olefin resin, a polyvinyl chloride resin, and a silicone resin, but it is not limited thereto.

[0052] Hereinafter the invention will be explained with reference to specific examples, but the invention is not limited to these examples.

[0053] In FIG. 1, the catheter part 1 is produced by extrusion molding from, for example, a urethane resin into a flexible tube member having a outer diameter of 0.3 to 20 mm and a thickness of 0.08 to 5 mm, with the inner diameter thereof slightly larger than the outer diameter of the blood vessel piercing internal needle 2 to be introduced therein, and the base end thereof connected with the hub part 9. As shown in FIG. 1, the hub part 9 produced by injection molding from, for example, 1,2-polybutadiene, is fitted with the flexible resin member 4. The flexible resin member 4 is produced by extrusion molding or injection molding from, for example, 1,2-polybutadiene. Since the blood flow amount differs depending on the application position, such as for dialysis, artery, vein, or introducer kit, the size of the flexible resin member 4 and the wing parts 6 is changed accordingly. For example, an outer diameter of 1.0 to 40 mm, a thickness of 0.08 to 10 mm, and a length of 3 to 100 mm can be adopted. Furthermore, an outer diameter of 1.2 to 30 mm, a thickness of 0.1 to 8 mm, and a length of 5.0 to 80 mm are further preferable. A pair of the flexible wings 6 produced by injection molding from a polyethylene elongate symmetrically on both right and left ends of the flexible resin member 4 in the direction substantially orthogonal to the axial direction of the catheter. The width of the wing parts 6 is 2 to 80 mm, and the length from the main body side to the end part is 5 to 100 mm. It is further preferable that the wing width is 3 to 70 mm, and the length from the main body side to the end part is 8 to 80 mm. The pressure parts 7 are formed preferably integrally with the wing parts on the upper surface of the wing parts 6. The height of the pressure parts is 0.8 to 50 mm, and is further preferably 1.0 to 40 mm.

[0054] As heretofore described, since the flexible resin member including a reinforcing tubular or pipe-like member capable of alleviating stress concentration is provided in the catheter part for pressuring and closing the catheter part therefrom, the stress can be alleviated compared with the conventional case of directly pressuring and closing the catheter part so that blood leakage can be prevented without generating breakage or cut-off of the catheter.

[0055] Furthermore, since the pressure parts are provided for pressuring and closing via the flexible resin member, breakage or cut-off of the catheter according to the excessive pressure by metal forceps in the conventional method can be restrained. Moreover, since the

pressure parts are provided in the intravascular catheter main body, an extra closing device needs not be prepared as well as the operation of taking out the internal needle is facilitated compared with the conventional method.

[0056] Furthermore, since the fixing mechanism capable of fixing the pressured state is provided, freedom of use of both hands necessary in the subsequent operation of connecting the external circuit such as a medicine liquid and a transfusion liquid is ensured. Moreover, since the releasing mechanism capable of easily releasing the fixed state is provided, the fixed state can be released without giving a pain to the patient. Since the pressure parts, the fixing mechanism and the releasing mechanism are provided integrally with the wing parts, a compact configuration, a good operativity, and improved economy and productivity can be achieved without giving a pain to the patient at the time of closing the catheter by pressing thereto as in the conventional method.

[0057] Furthermore, since the hub part is provided at the base end side of the flexible resin member, the flexible resin member needs not be disposed between the hub part and the connector part so that the hub part and the connector part are provided adjacently for allowing the integration. Accordingly, the number of parts is reduced so that the productivity and economy are improved as well as the entire length is shortened to achieve the compactness and improve the handling convenience.

[0058] Moreover, since the flexible resin member is bonded with the catheter part, the catheter restoration force after being released from the pressured and closed state can be improved. Furthermore, in the case where the flexible resin member is made from a thermally contractible material, it can be fixed on the outer surface of the catheter without the need of using an adhesive.

[0059] Furthermore, even in the case where the catheter is used as the introducer kit for introducing an external catheter such as a guide wire, blood leakage after taking out the internal needle can be prevented as well as, since the wing parts can be fixed and maintained in the closed state, blood leakage can be restrained at the time of introducing the external catheter such as a guide wire by nipping the wing parts for pressuring the flexible resin pipe-like member.

Claims

1. An intravascular catheter comprising:

    a catheter (1);
    an internal needle (2) disposed through the catheter (1);
    a blood leakage preventing member for preventing leakage of blood by compressing the catheter (1), the blood leakage preventing member including first and second wings (6) disposed on either side of the catheter (1), the wings respectively having pressure means (7) for applying pressure from opposite sides when the wings are pressed together, thereby to compress the catheter (1); and
    releasable fixing means (8) for fixing the pressure means (7) in a pressuring state in which the catheter (1) is compressed and being releasable for releasing the pressure means (7) from the pressuring state,

    characterised in that:

    a flexible tubular resin member (4) surrounds the outer surface of the catheter (1);
    said wings (6) when pressed together compress the tubular resin member (4) between them; and
    said releasable fixing means comprises one of:

    (a) a tab member (8, 12) carried by a first one of said wings (6) and extending in the same direction as said first wing, the tab member having:

        a fixing end (8) engageable with a fixing element (8) on the other wing to lock the wings in the pressuring state, and
        a plate portion (12) which is squeezable towards said first wing to lift the fixing end (8) to release from the pressuring state;

    (b) complementary projecting and recessed fitting parts, one parts provided on each wing (6), the pressure means (7) being fixable in the pressuring state by engagement of the projecting fitting part with the recessed fitting part;
    (c) a pair of interengageable latching elements on said wings respectively, which are engageable to lock the wings in said pressuring state, said wings having a rolled shape both when released and when in the pressuring state, said latching elements being released by pushing the wings together.

2. The intravascular catheter according to claim 1, wherein at least one of the pressure means (7) and releasable fixing means (8) is integral with the wings (6)

3. The intravascular catheter according to either one of claims 1 or 2, wherein the catheter (1) and the

flexible resin member (4) are fixed by welding. fusion or an adhesive

4. The intravascular catheter according to either one of claims 1 or 2, wherein the flexible resin member (4) is a thermally contractible member, fixed on the catheter (1) outer surface by thermal contraction

5. The intravascular catheter according to any one of the preceding claims, wherein a hub (9) is provided on the proximal end of the flexible resin member (4).

6. The intravascular catheter according to any one of the preceding claims, wherein the flexible resin member (4) has a tubular shape with a rhomboidal cross-sectional shape, the ratio A/B of the thickness of the thickest part A of the tube wall and the thinnest part B of the tube wall being in the range between 1 and 10

7. The intravascular catheter according to any one of claims 1 to 5, wherein the flexible resin member (4) has a tubular shape with an elliptical cross-sectional shape, the ratio C/D of the longer axis C and the shorter axis D being in the range between 1 and 4

Patentansprüche

1. Intravaskulärer Katheter mit:

   einem Katheter (1);
   einer Innennadel (2), die durch den Katheter (1) hindurch angeordnet ist;
   einem Blutaustrittsverhinderungselement zum Verhindern eines Austretens von Blut durch ein Zusammendrücken des Katheters (1), wobei das Blutaustrittsverhinderungselement einen ersten und einen zweiten Flügel (6) hat, die an jeder Seite von dem Katheter (1) angeordnet sind, wobei die Flügel jeweils eine Druckeinrichtung (7) haben, um einen Druck von entgegengesetzten Seiten dann aufzubringen, wenn die Flügel zusammengedrückt werden, wodurch der Katheter (1) zusammengedrückt wird; und
   einer lösbaren Fixiereinrichtung (8) für ein Fixieren der Druckeinrichtung (7) in einem mit Druck beaufschlagten Zustand, bei dem der Katheter (1) zusammengedrückt ist, und wobei sie lösbar ist, um die Druckeinrichtung (7) aus dem mit Druck beaufschlagten Zustand zu entlasten,

   dadurch gekennzeichnet, dass
   ein flexibles röhrenartigen Harzelement (4) die Außenfläche von dem Katheter (1) umgibt;
   die Flügel (6), wenn sie zusammengedrückt sind, das röhrenartige Harzelement (4) zwischen ihnen zusammendrücken; und wobei
   die lösbare Fixiereinrichtung folgendes aufweist:

   entweder

   (a) ein Vorsprungselement (8, 12), das durch einen ersten Flügel (6) getragen ist und sich in der gleichen Richtung wie der erste Flügel erstreckt, wobei das Vorsprungselement Folgendes aufweist:

   ein Fixierende (8), das mit einem Fixierelement (8) an dem anderen Flügel in Eingriff bringbar ist, um die Flügel in dem mit Druck beaufschlagten Zustand zu arretieren, und
   einen Plattenabschnitt (12), der zu dem ersten Flügel hin zusammendrückbar ist, um das Fixierende (8) anzuheben, um den mit Druck beaufschlagten Zustand zu entlasten; oder

   (b) komplementäre Zubehörteile mit einem Vorsprung bzw. mit einer Vertiefung, wobei ein Teil an jedem Flügel (6) vorgesehen ist, wobei die Druckeinrichtung (7) in dem mit Druck beaufschlagten Zustand durch den Eingriff des mit dem Vorsprung versehenen Zubehörteiles mit dem mit der Vertiefung versehenen Zubehörteil fixierbar ist; oder
   (c) einem Paar an miteinander in Eingriff bringbaren Einrastelementen jeweils an den Flügeln, die in Eingriff bringbar sind, um die Flügel in dem mit Druck beaufschlagten Zustand zu arretieren, wobei die Flügel eine Rollenform haben sowohl wenn sie freigegeben sind als auch in dem mit Druck beaufschlagten Zustand, wobei die Einrastelemente freigegeben werden, indem die Flügel zueinander gedrückt werden.

2. Intravaskulärer Katheter gemäß Anspruch 1, wobei zumindest entweder die Druckeinrichtung (7) oder die lösbare Fixiereinrichtung (8) mit den Flügeln (6) einstückig ist.

3. Intravaskulärer Katheter gemäß einem der Ansprüche 1 oder 2, wobei
der Katheter (1) und das flexible Harzelement (4) fixiert sind durch ein Schweißen, Kleben oder ein Haftmittel

4. Intravaskulärer Katheter gemäß einem der Ansprüche 1 oder 2, wobei

das flexible Harzelement (4) ein thermisch kontrahierbares Element ist, das an der Außenfläche des Katheters (1) durch thermisches Kontrahieren befestigt ist.

5. Intravaskulärer Katheter gemäß einem der vorherigen Ansprüche, wobei
eine Buchse (9) an dem proximalen Ende von dem flexiblen Harzelement (4) vorgesehen ist.

6. Intravaskulärer Katheter gemäß einem der vorherigen Ansprüche, wobei
das flexible Harzelement (4) eine röhrenartige Form mit rhomboidartigen Querschnittsform hat, wobei das Verhältnis A/B der Dicke von dem dicksten Teil A der Röhrenwand und dem dünnsten Teil B der Röhrenwand in dem Bereich zwischen 1 und 10 liegt.

7. Intravaskulärer Katheter gemäß einem der Ansprüche 1 bis 5, wobei
das flexible Harzelement (4) eine röhrenartige Form mit einer elliptischen Querschnittsform hat, wobei das Verhältnis C/D von der längeren Achse C und der kürzeren Achse D in dem Bereich zwischen 1 und 4 liegt.

Revendications

1. Cathéter intravasculaire, comprenant :

un cathéter (1) ;
une aiguille interne (2) disposée à travers le cathéter (1) ;
un élément d'empêchement de fuite sanguine pour empêcher une fuite de sang en comprimant le cathéter (1), l'élément d'empêchement de fuite sanguine comprenant une première et une seconde patte (6) disposées de part et d'autre du cathéter (1), les pattes comprenant respectivement des moyens de pressage (7) pour appliquer une pression depuis des côtés opposés quand les pattes sont pressées ensemble, pour comprimer ainsi le cathéter (1) ; et
des moyens de fixation libérables (8) pour fixer les moyens de pressage (7) dans un état de pressage dans lequel le cathéter (1) est comprimé, et qui sont libérables pour libérer les moyens de pressage (7) depuis l'état de pressage,

caractérisé en ce que :

un élément en résine tubulaire flexible (4) entoure la surface extérieure du cathéter (1) ;
lesdites pattes (6), lorsqu'elles sont pressées ensemble, compriment l'élément en résine tubulaire (4) entre elles ; et
lesdits moyens de fixation libérables comprennent l'une des dispositions suivantes :

(a) un élément en languette (8, 12) porté par une première patte (6) et s'étendant dans la même direction que ladite première patte, l'élément en languette ayant :

une extrémité de fixation (8) susceptible d'être engagée avec un élément de fixation (8) sur l'autre patte pour bloquer les pattes dans l'état de pressage, et
une portion en plaquette (12) qui peut être écrasée vers ladite première patte pour soulever l'extrémité de fixation (8) et la relâcher de l'état de pressage ;

(b) des parties d'engagement complémentaires en projection et en évidement, une partie prévue sur chaque patte (6), les moyens de pressage (7) pouvant être fixés dans l'état de pressage par engagement de la partie d'engagement en projection avec la partie d'engagement en évidement ;
(c) une paire d'éléments de verrouillage susceptibles d'être mutuellement engagés, prévus respectivement sur lesdites pattes, qui sont susceptibles d'être engagés pour bloquer les pattes dans ledit état de pressage, lesdites pattes ayant une forme enroulée aussi bien dans l'état relâché que dans l'état de pressage, lesdits éléments de verrouillage étant libérés en poussant les pattes ensemble.

2. Cathéter intravasculaire selon la revendication 1, dans lequel l'un au moins des moyens de pressage (7) et des moyens de fixation libérables (8) est intégré avec les pattes (6).

3. Cathéter intravasculaire selon l'une ou l'autre des revendications 1 et 2, dans lequel le cathéter (1) et l'élément en résine flexible (4) sont fixés par soudage, par fusion, ou par un adhésif.

4. Cathéter intravasculaire selon l'une ou l'autre des revendications 1 et 2, dans lequel l'élément en résine flexible (4) est un élément thermiquement contractible, fixé sur la surface extérieure du cathéter (1) par contraction thermique.

5. Cathéter intravasculaire selon l'une quelconque des revendications précédentes, dans lequel un moyeu (9) est prévu sur l'extrémité proximale de

l'élément en résine flexible (4)

6. Cathéter intravasculaire selon l'une quelconque des revendications précédentes, dans lequel l'élément en résine flexible (4) a une forme tubulaire avec section transversale en forme de losange, le rapport A/B de l'épaisseur de la partie la plus épaisse A de la paroi tube et celle de la partie la plus mince B de la paroi du tube étant dans la plage entre 1 et 10.

7. Cathéter intravasculaire selon l'une quelconque des revendications 1 à 5, dans lequel élément en résine flexible (4) a une forme tubulaire avec une section transversale en forme d'ellipse, le rapport C/D du grand axe C et du petit axe D étant dans la plage entre 1 et 4.

FIG. 1

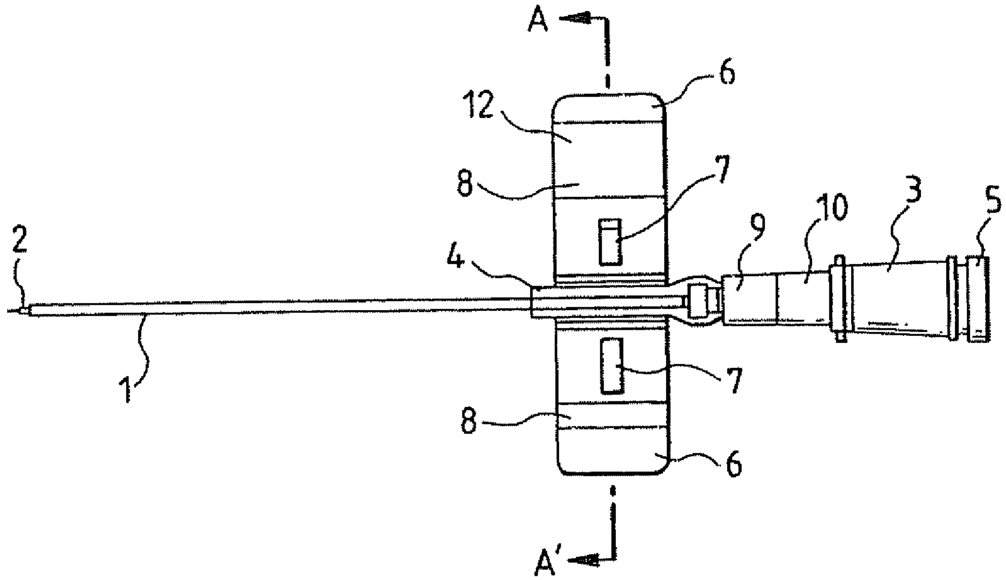

FIG. 2

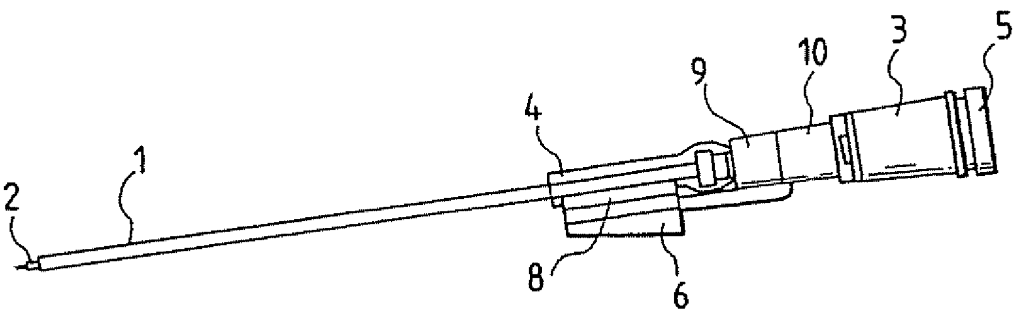

FIG. 3

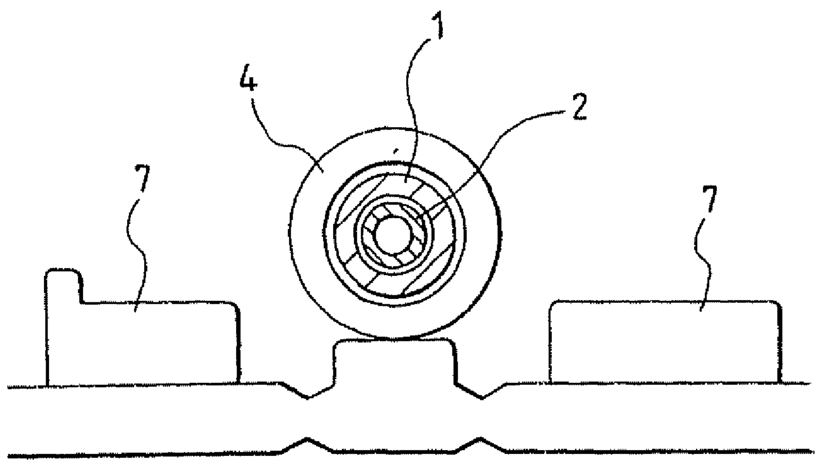

FIG. 4

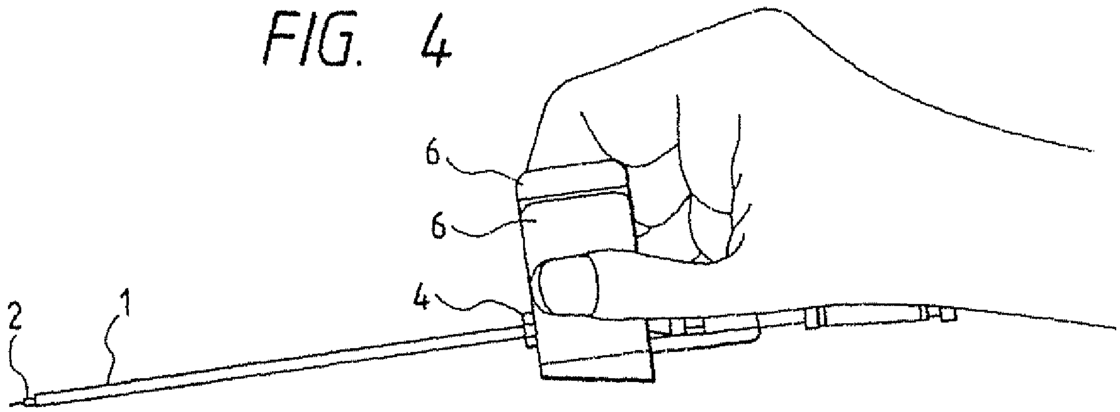

FIG. 5

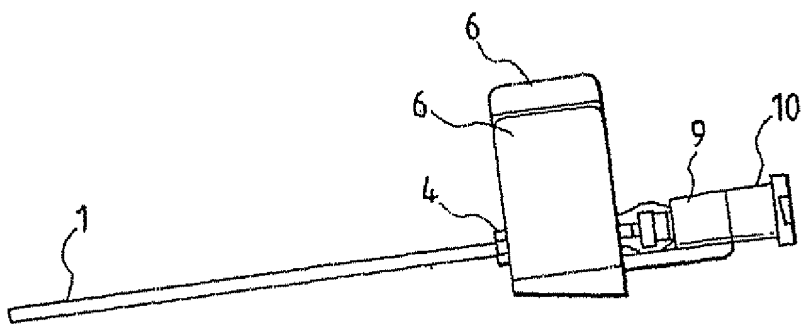

FIG. 6

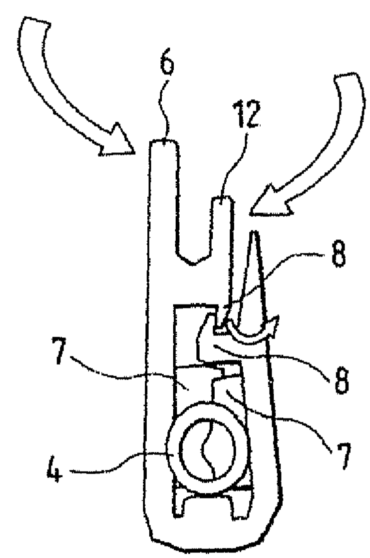

FIG. 7

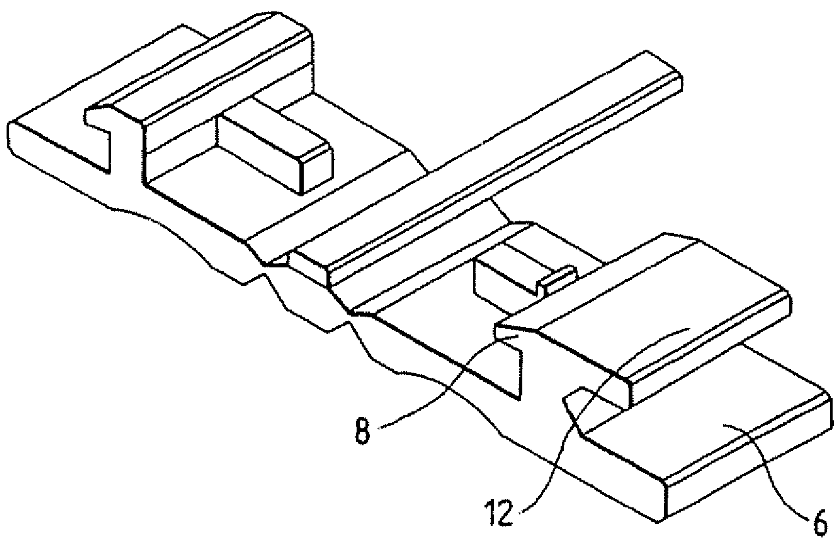

FIG. 8

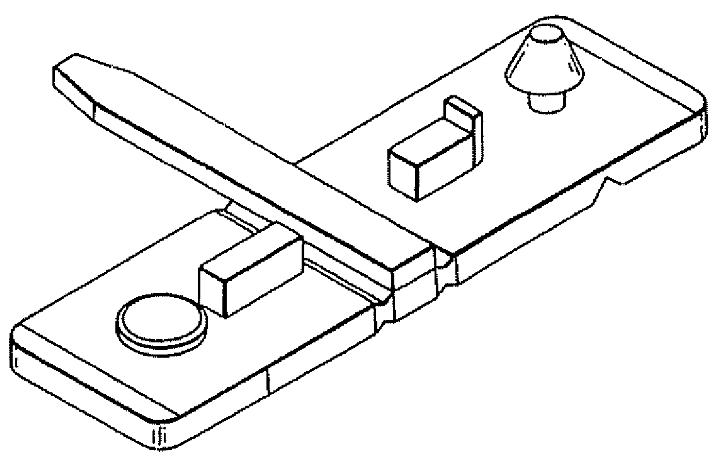

FIG. 9(A)

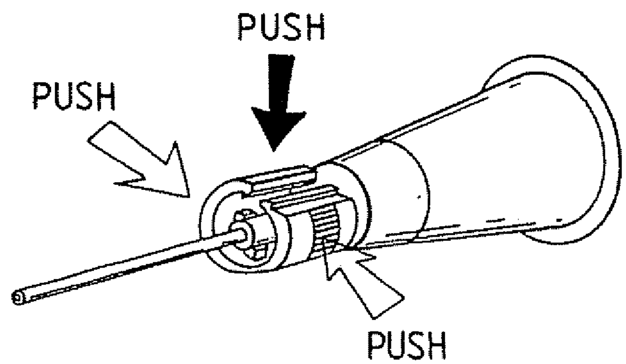

FIG. 9(B)

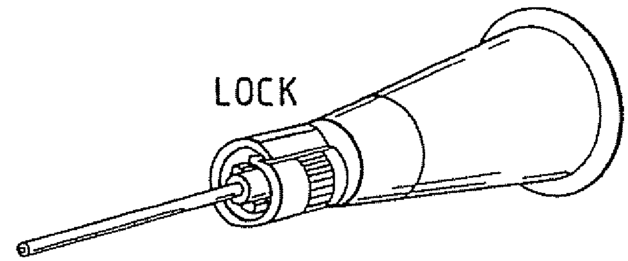

FIG. 9(C)

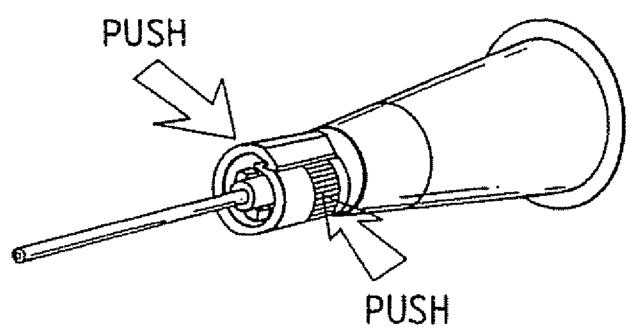

FIG. 9(D)

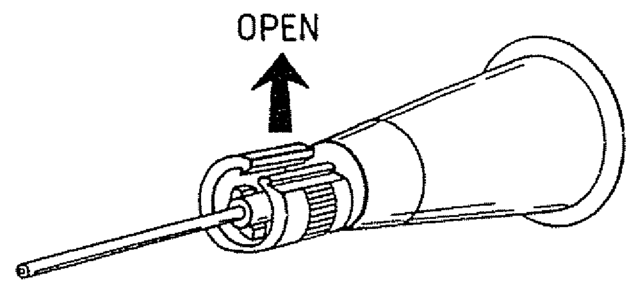

FIG. 10

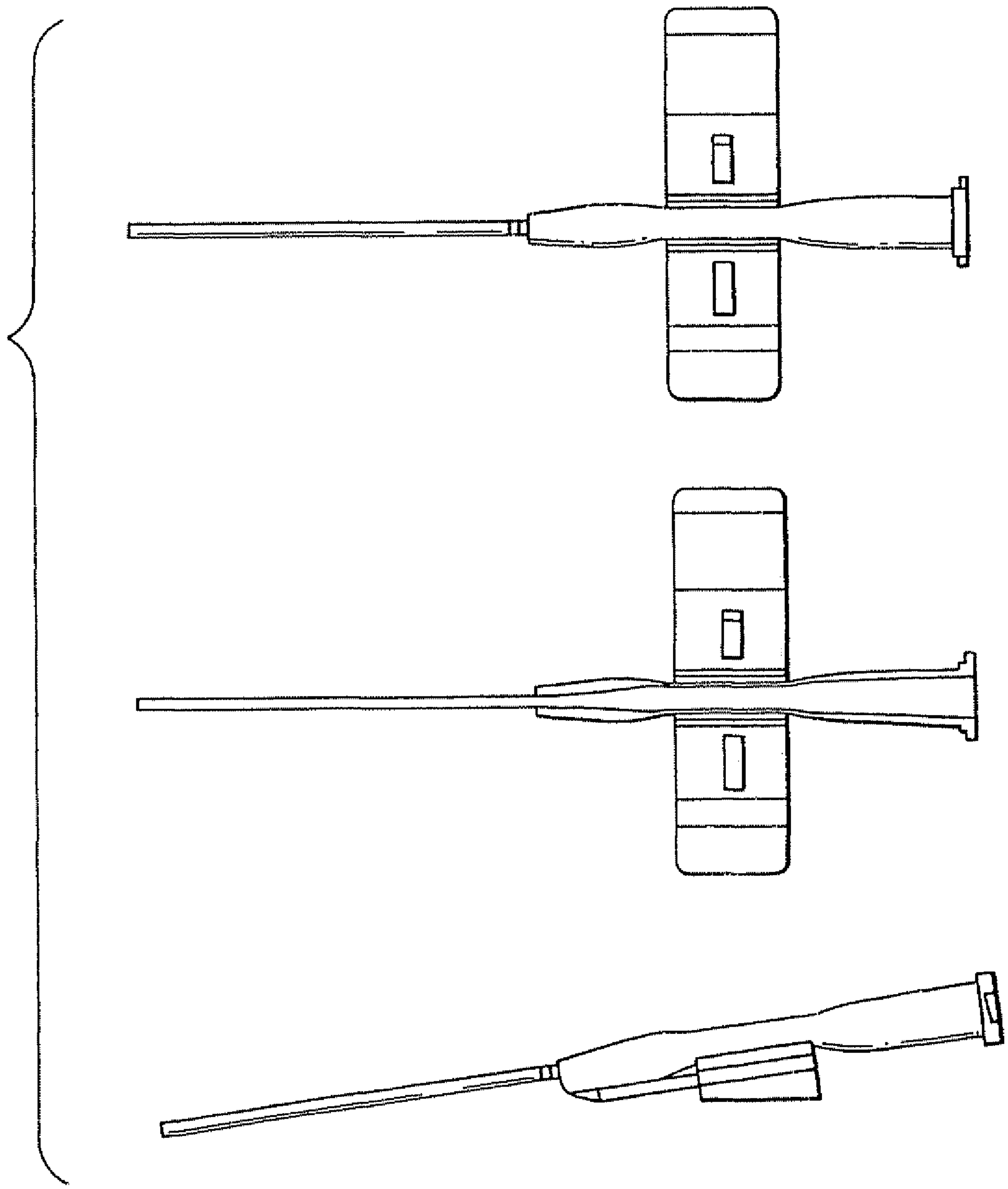

FIG. 11(A)

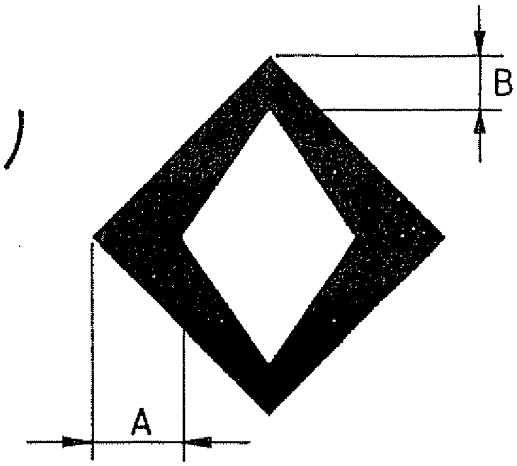

FIG. 11 (B)

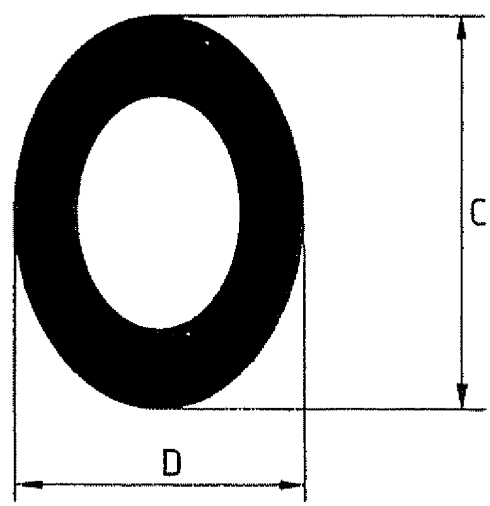

FIG. 12

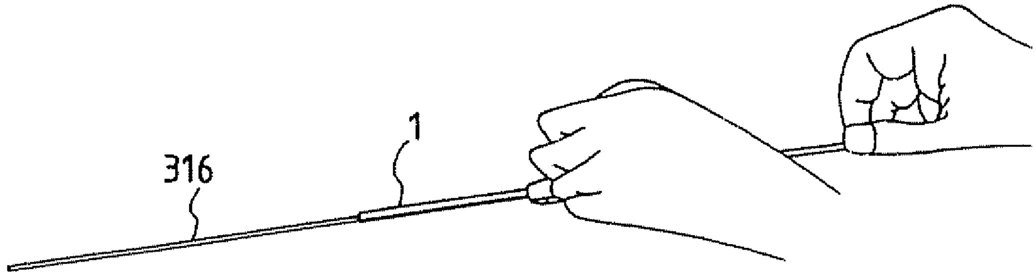

FIG. 13
PRIOR ART

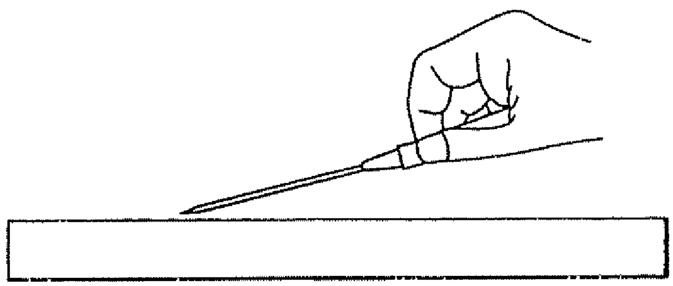

FIG. 14
PRIOR ART